

EXHIBIT 129

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

- - -

4 IN RE: NATIONAL : HON. DAN A. POLSTER
5 PRESCRIPTION OPIATE :
6 LITIGATION :
7 :
8 APPLIES TO ALL CASES : NO.
9 :
10 : 1:17-MD-2804

11 - HIGHLY CONFIDENTIAL -
12 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

- - -

13 JANUARY 16, 2019

- - -

14 Videotaped sworn deposition of
15 TRACEY L. NORTON, taken pursuant to
16 notice, was held at BEST WESTERN LEHIGH
17 VALLEY HOTEL & CONFERENCE CENTER, 300
18 Gateway Drive, Bethlehem, Pennsylvania,
19 beginning at 8:51 a.m., on the
20 abovedate, before Margaret M. Reihl, a
21 Registered Professional Reporter,
22 Certified Shorthand Reporter, Certified
23 Realtime Reporter, and Notary Public.

- - -

24 GOLKOW LITIGATION SERVICES
25 877.370.3377 ph | 917.591.5672 fax
26 deps@golkow.com

1 don't know for sure.

2 (Document marked for
3 identification as Par-Norton Deposition
4 Exhibit No. 2.)

5 BY MR. BUCHANAN:

6 Q. Ma'am, I'm passing over what
7 we're marking as Exhibit 2 to your deposition.
8 I have a few more questions before we get into
9 that, but you will have a chance to review that
10 at the appropriate time.

11 So you were at Watson, just to
12 confirm, until 2009?

13 A. Yes.

14 Q. And do you remember roughly how
15 soon before you left Watson that this -- or when
16 relative to your departure from Watson this
17 meeting with Anda and the DEA occurred?

18 A. I do not recall.

19 Q. Okay. Let's look now at
20 Exhibit 2 to your deposition. This is a
21 document during your time at Endo. It was
22 produced to us by, I think, H.D. Smith.

23 MS. VANNI: Counsel, I just want
24 to clarify she was not an Endo employee.

1 off, they were on board anytime that I
2 interacted with them.

3 BY MR. BUCHANAN:

4 Q. Right.

5 So once you showed them diligence
6 that you had done -- or investigation that had
7 been done, a review of data that had been
8 conducted, people were willing to accept the
9 conclusion, fair?

10 A. Yes.

11 Q. Okay. But you've got to do the
12 diligence, you've got to do the digging, you had
13 to make the case?

14 MS. VANNI: Object to form.

15 THE WITNESS: Yes. We're not
16 going to, you know, stop shipping to a
17 customer without justification, sure.

18 BY MR. BUCHANAN:

19 Q. So it's really hard to develop
20 that justification if you're not doing due
21 diligence on customers, correct?

22 MS. VANNI: Object to form.

23 THE WITNESS: No, because sales
24 was contacting me. If they had a

1 DEA throughout my time at Qualitest. I don't
2 know which -- what instance you are referring
3 to, but we did have occasions where we had
4 violation letters.

5 Q. Okay. And do you recall -- do
6 you recall getting a letter not from the DEA,
7 but from the U.S. Attorney directed to you,
8 telling you that there were egregious violations
9 and you had a week to sit down with them to talk
10 about your fine?

11 MS. VANNI: Object to form.

12 THE WITNESS: I don't recall
13 that.

14 THE VIDEOGRAPHER: Counsel, could
15 we go off the record just momentarily?

16 MR. BUCHANAN: Yeah.

17 THE VIDEOGRAPHER: Going off the
18 record. The time is now 9:53 a.m.

19 (Brief recess.)

20 THE VIDEOGRAPHER: Back on the
21 record. The time is 9:55 a.m.

22 (Document marked for
23 identification as Par- Norton Deposition
24 Exhibit No. 3)

1 BY MR. BUCHANAN:

2 Q. I'm passing you, Ms. Norton, a
3 copy of Exhibit 3 to your deposition. This is a
4 letter from the U.S. Attorney, U.S. Department
5 of Justice, Joyce Vance, United States Attorney,
6 I guess for the Northern District of Alabama,
7 it's dated September 30, 2014, 1060.2. If you
8 could pull it up, please.

9 And do you see before -- I guess
10 you read the content of it, ma'am, do you see
11 you're on this exchange?

12 A. Yes, I do.

13 Q. Okay. You are the point of
14 contact from the Department of Justice on this
15 particular correspondence from the U.S.
16 Attorney's Office?

17 A. Yes.

18 Q. It says "Ms. Hernandez, please
19 find attached the Notice of Intent to Seek Civil
20 Penalties."

21 Do you see that on the cover, the
22 cover e-mail?

23 A. Yes.

24 Q. And this is September 30, 2014,

1 it's a couple weeks, it looks like, before you
2 are engaging with H.D. Smith in your job search.

3 Do you see that?

4 A. The date, yes, September 30.

5 Q. Is that correct?

6 A. Mm-hmm.

7 Q. Okay. So you get this letter.

8 Please feel free to look at it. It's a
9 follow-up letter to a teleconference you had had
10 a week earlier on September 22, 2014.

11 Do you see that?

12 A. Yes.

13 Q. Okay. It says, "The audit
14 revealed alarming deviations of Schedule II and
15 Schedule III controlled substances in violation
16 of 21 CFR 1304.21, other statutes, you failed to
17 account for and properly maintain records of the
18 following."

19 And then it's got a list of seven
20 items there. And, I'm sorry, are you still
21 reading?

22 A. Yes.

23 Q. Okay.

24 A. (Witness reviews document.)

1 Q. And can you highlight the items,
2 please.

3 So we see item one, Hydrocodone
4 10, 325 milligrams, that's Hydrocodone
5 10 milligrams, 325 milligrams of acetaminophen,
6 is that what that would be?

7 A. Yes.

8 Q. And so, you know, about roughly
9 1200 bottles unaccounted for, right?

10 A. Mm-hmm.

11 MS. VANNI: Objection to the
12 form.

13 THE WITNESS: Doesn't necessarily
14 mean they were unaccounted for as much
15 as the recordkeeping of them.

16 BY MR. BUCHANAN:

17 Q. Well, it says "GB," and GB is --

18 A. Generics Bidco.

19 Q. And Generics Bidco was one of the
20 operating entities of Qualitest, correct?

21 A. Yes.

22 Q. One of the registrants with the
23 DEA, correct?

24 A. Yes.

1 Q. And there was another registrant
2 with the DEA that also operated under Qualitest,
3 correct?

4 A. Yes.

5 Q. And what was the entity's name?

6 A. Vintage -- Vintage
7 Pharmaceuticals.

8 Q. Right.

9 So what we see here are some 1200
10 bottles of Hydrocodone with 10 milligrams, 1300
11 bottles of hydrocodone seven and a half
12 milligrams, more in different -- in different
13 allocations. 816 bottles of Oxycodone.

14 What's Oxycodone 30 milligrams,
15 ma'am?

16 A. What is it?

17 Q. Yeah.

18 A. I don't --

19 Q. Is it a generic of Oxycontin?

20 A. Yes.

21 Q. Okay. And then on the next page,
22 it says "The DEA's inspection revealed an
23 overall careless and haphazard recordkeeping
24 practice at GB" -- that's the Qualitest entity,

1 correct?

2 A. Mm-hmm.

3 Q. -- "as demonstrated by, among
4 other things, deviations exceeding 9 million
5 tablets."

6 Did I read that correctly?

7 A. Yes.

8 Q. It continues, the follow on
9 paragraph, "GB's recordkeeping violations, in
10 particular, as evidenced by the several-million
11 tablet deviations are" -- and what did they say?

12 A. I'm sorry, where are you looking?
13 Failure to maintain --

14 Q. "GB's recordkeeping violations,
15 in particular" --

16 A. Yes.

17 Q. -- "as evidenced by the
18 several-million tablet deviation are," and what
19 do they say?

20 A. -- "egregious and evidence a
21 complete disregard of GB's statutory and
22 regulatory obligations."

23 Q. That's not good.

24 MS. VANNI: Object to form.

1 THE WITNESS: The way the DEA
2 and/or the Attorney General words a
3 violation letter is meant to -- meant to
4 be exaggerated for impact.

5 BY MR. BUCHANAN:

6 Q. "Egregious and evidence of a
7 complete disregard of your statutory and
8 regulatory obligation," that's not good, right?

9 MS. VANNI: Object to form.

10 THE WITNESS: It's not -- it's
11 not really descriptive of the situation.

12 BY MR. BUCHANAN:

13 Q. It's certainly not the way a
14 company who is a registrant in a closed system
15 of controlled substance distribution should be
16 contacting itself, right?

17 MS. VANNI: Object to form.

18 THE WITNESS: These letters are
19 also meant to point out violations --

20 BY MR. BUCHANAN:

21 Q. Can you answer my question?

22 A. I'm sorry, what was the question?

23 Q. Yes. It's not the way in which a
24 manufacturer and registrant of a controlled

1 MS. VANNI: Thank you.

2 MR. BUCHANAN: I need one back,
3 actually. Keep that in the folder.

4 BY MR. BUCHANAN:

5 Q. We're marking as Exhibit 4 a
6 summary of Qualitest shipments.

7 MS. VANNI: Counsel, I'm assuming
8 this is produced in native, but could
9 you read the Bates number into this.

10 MR. BUCHANAN: Yeah, the Bates
11 number is -- so this -- we've asked you
12 for your shipping information, and
13 you've pointed us to this particular
14 document. I guess I could ask the
15 witness to sum it, but that would be a
16 poor use of our day together, but the
17 Bates numbers at the top Par Opioid
18 MDL0001596805, Par Opioid
19 MDL00015968013-68019. I believe these
20 are spreadsheets that you have produced
21 to us.

22 MS. VANNI: And it's one page or
23 two?

24 MR. BUCHANAN: Mine is two pages.

1 suspicious order monitoring system."

2 Do you see that, ma'am?

3 A. Yes.

4 Q. Okay. And it talks about
5 Qualitest and its locations and then there's a
6 sentence attributed to you.

7 Ms. Hernandez was aware of the
8 chargeback system utilized by manufacturers,
9 including Qualitest, but stating that the firm
10 has not reviewed it.

11 Do you see that?

12 A. Yes.

13 Q. Do you recall discussing that
14 with the DEA?

15 A. Yes, I do.

16 Q. Okay. And that accurately sets
17 forth at least that portion of the discussion,
18 right?

19 A. Yes.

20 Q. Okay. "Ms. Hernandez stated the
21 firm's suspicious order monitoring system is a
22 work in progress."

23 Do you see that?

24 A. Yes.

1 pharmacies purchasing large quantities of
2 oxycodone and hydrocodone products from
3 Qualitest's customers. The graph showed the
4 pharmacies in Florida purchased very large
5 quantities of Qualitest's oxycodone products.
6 Also, the graphs show that pharmacies in Texas
7 and California purchased large quantities of
8 Qualitest's hydrocodone products.

9 Ms. Hernandez, Ms. Hudson and Ms. Patel were
10 completely unaware of where Qualitest products
11 were ending up.

12 As of that point in time, ma'am,
13 were you completely unaware of where Qualitest's
14 products were ending up?

15 A. No. What this refers to is that
16 we were unaware of the secondary customers. So
17 we ship to the customers and we were aware who
18 we were shipping to and, you know, the
19 information for them, but we did not have
20 visibility of the customers that they then
21 shipped to.

22 Q. Right, as of that point in time,
23 ma'am, you were not looking at really the
24 customers of customers in terms of what they

1 were receiving, right?

2 A. Correct. We didn't have data
3 available to us.

4 Q. Well, there is chargeback data
5 that the company ultimately looked at, fair?

6 MS. VANNI: Object to form.

7 THE WITNESS: Yes, that gave
8 us --

9 BY MR. BUCHANAN:

10 Q. In fact, the DEA told you you
11 need to be looking at that, right?

12 MS. VANNI: Object to form.

13 THE WITNESS: The DEA told us
14 that we should look at it because that's
15 what they were hearing from other
16 manufacturers, that they were looking
17 into that and trying to see if they
18 could get data from it.

19 BY MR. BUCHANAN:

20 Q. And, in fact, you contracted to
21 after this meeting and started to implement a
22 process where you reviewed and considered
23 chargeback data, correct?

24 A. Yes, we did try.

1 Q. Okay. You, in fact, did
2 implement the consideration of chargeback data
3 as part of your SOMS process, correct?

4 A. Not while I was at Qualitest. It
5 was something -- I don't know if anything was --
6 happened afterwards, but while I was there, we
7 were not able to get any good data out of it.

8 Q. Okay. Let's pause and see if I
9 can refresh your memory on that during our
10 examination today.

11 A. Sure.

12 Q. It then continues that "SC Levin
13 stated that Qualitest must review the chargeback
14 information which they have access to,
15 immediately address deficiencies in their
16 suspicious order monitoring system, have
17 compliance people visit their customers to
18 review their suspicious order monitoring system
19 and review the top customers of their customers
20 and pay visits to pharmacies that purchase their
21 products. SC Levin advised Ms. Hernandez that
22 Qualitest must know their customers and maintain
23 a due diligence file on them. SC Levin stated
24 Qualitest's current system as explained to him

1 A. Yes.

2 Q. So you were the head of DEA
3 compliance. You hired Mr. Brantley into your
4 group, correct?

5 A. Yes, I hired Larry first,
6 Mr. Shaffer and then later hired Eric.

7 Q. When did you bring in Mr. -- is
8 it Shaffer or Shaffer?

9 A. Shaffer.

10 Q. It's the two Fs that are throwing
11 me there.

12 A. I'm not sure exactly when.

13 Q. I assume his e-mail address is
14 spelled right. All right. So when did you hire
15 him, by the way?

16 A. I'm not sure on exact -- the
17 exact date, but he was, I believe, my first
18 hire.

19 Q. After the meeting with the DEA?

20 A. No. After getting to Qualitest.

21 Q. Okay. And he was, if I
22 understand right, he was more in this quota
23 management function, right?

24 A. He was at the company, however,

1 he actually had a -- he had handled suspicious
2 order monitoring previously.

3 Q. Got you.

4 All right. So let's look at
5 this. This is an e-mail from Mr. Shaffer to
6 Mr. Brantley early October 2013, subject SOMS
7 info, right?

8 A. Yes.

9 Q. SOMS violations as a spreadsheet,
10 SOMS doc from 2013 and a SOMS presentation,
11 right?

12 A. Yes.

13 Q. Okay. Do you remember during
14 your time at the company one of the things you
15 were tracking was who was getting in trouble?

16 MS. VANNI: Object to form.

17 THE WITNESS: Yes.

18 BY MR. BUCHANAN:

19 Q. And you had an Excel spreadsheet
20 that you put together and kind of tracked what
21 was happening with different registrants who was
22 getting gigged and written up with big fines and
23 stuff like that, right?

24 MS. VANNI: Object to form.

1 THE WITNESS: Yes.

2 BY MR. BUCHANAN:

3 Q. Giggled is a confusing term.

4 Getting, what, registrations

5 pulled, fined, civil actions, suspension orders,

6 all that kind of stuff?

7 A. Yes, we were tracking it.

8 Q. Okay. And so one of the things a
9 reasonable company does, and I guess this was a
10 responsible thing to do?

11 MS. VANNI: Object to form.

12 THE WITNESS: I think so. I
13 think it helped to -- it helped to teach
14 others in the company what ramifications
15 there were if something were to go
16 wrong.

17 BY MR. BUCHANAN:

18 Q. And that's something that you
19 have in a compliance department as a bit of an
20 issue from time to time, right?

21 MS. VANNI: Object to form.

22 THE WITNESS: No company is
23 perfect.

24 BY MR. BUCHANAN:

1 Q. Certainly not, certainly not, and
2 nor are people.

3 But one of the issues you have in
4 a compliance department is sometimes some
5 tension between compliance with what a
6 responsible company would do or reasonable
7 company would do or the regulations require and
8 what the business people want, right?

9 MS. VANNI: Objection.

10 THE WITNESS: I wouldn't
11 necessarily say that there's tension
12 from the aspect of, you know, everybody
13 knows that you have to comply with the
14 DEA regulations. It's a matter of
15 education, it really is.

16 BY MR. BUCHANAN:

17 Q. And so one of the things you did
18 was compile a list of all the bad things that
19 could happen to us as a business with 70%
20 controlled substances if we don't comply, right?

21 MS. VANNI: Object to form.

22 THE WITNESS: Yes.

23 BY MR. BUCHANAN:

24 Q. Because this, you know, this is a

1 -- this could be a devastating consequence if we
2 don't comply, right?

3 MS. VANNI: Object to form.

4 THE WITNESS: Yes.

5 BY MR. BUCHANAN:

6 Q. Fair, yeah.

7 So one of the things that's
8 helpful in certainly getting management's
9 attention is you should know distribution
10 facilities have been closed, right?

11 A. Mm-hmm.

12 Q. That's a yes answer?

13 A. Yes. Sorry.

14 Q. You should know that tens of
15 millions of dollars in fines have been imposed
16 against certain distributors, right?

17 MS. VANNI: Object to form.

18 THE WITNESS: Yes.

19 BY MR. BUCHANAN:

20 Q. You should know that we have a
21 distributor license, right?

22 A. Yes.

23 Q. And if we're not doing our job,
24 this could be devastating, right?

1 MS. VANNI: Object to form.

2 THE WITNESS: Well, it could
3 impact the business, yes.

4 BY MR. BUCHANAN:

5 Q. Certainly.

6 And so you bring these items to
7 the attention of people above you to say, look,
8 this could affect our pocketbook, right?

9 MS. VANNI: Objection.

10 THE WITNESS: Actually, no. The
11 reason that we use these was because I
12 knew that the electronic system that I
13 wanted to implement was very expensive,
14 and I needed to have adequate
15 justification to support that system
16 because -- because we did have something
17 in place, so I knew that the feedback I
18 would get is that we were complying with
19 the regulation. So I wanted to show
20 them some of the things that the other
21 companies were doing that DEA
22 categorized as not enough.

23 BY MR. BUCHANAN:

24 Q. Right. I mean, basically, you're

1 saying I needed to make sure I could get some
2 budget to make this happen, so I had to show the
3 other side of not doing it?

4 MS. VANNI: Object to form.

5 THE WITNESS: I was expecting
6 more resistance, yes.

7 BY MR. BUCHANAN:

8 Q. Okay. And so you put together
9 this schedule, and let's look at the -- let's be
10 clear, I guess, because I may not have time to
11 come back to this today.

12 Some of what we see here in the
13 SOMS violations are, for example, we see a
14 reference to Walgreens.

15 MR. BUCHANAN: Could we go to
16 606.4. Can you blow up this one right
17 here, if you can see my finger. Thank
18 you, yeah. My eyes are failing me,
19 guys. Sorry about that.

20 MR. SCHACK: Counsel, do you have
21 any other copies of this exhibit that
22 you can share?

23 MR. BUCHANAN: There's an extra
24 floater if somebody can pass the floater

1 down.

2 MR. SCHACK: Thank you.

3 BY MR. BUCHANAN:

4 Q. Okay. All right. So this is
5 suspension order that you tracked, a suspension
6 of a DEA license relating to a Walgreens
7 distribution center in Jupiter, Florida.

8 Do you remember that?

9 A. Yes.

10 Q. Do you remember -- you were aware
11 of that when it happened in 2012, right, as
12 somebody who reads the Federal Register, as
13 somebody who attends DEA conferences?

14 A. Yes.

15 Q. Okay. And then off to the right
16 we see really what you guys were doing, right,
17 and this is your drug that was being shipped in
18 to Florida, right?

19 MS. VANNI: Object to the form.

20 THE WITNESS: I can't read it.

21 BY MR. BUCHANAN:

22 Q. Yeah, it's a challenge with, I
23 don't know, spreadsheets. There's a
24 heading that's --

1 MR. BUCHANAN: Bradley, I'm
2 sorry, I think it's confusing for people
3 if you do it the way you've done it,
4 because at the top it says "Violation."

5 BY MR. BUCHANAN:

6 Q. Let's just read across the top
7 together, ma'am. You see Violation For --
8 there's Date, Violation For: Company, Violation,
9 Penalty, a web link, What they did, and What we
10 are doing.

11 Do you see that?

12 A. Yes.

13 Q. Okay. So then there's that
14 reference for the Walgreens facility that we
15 were just looking at, and you see there's a
16 narrative description of what happened with that
17 one?

18 A. Yes.

19 MR. BUCHANAN: And then I need
20 you to blow up, if you could, Bradley,
21 the units all the way to the right.
22 Keep going. Can you make the box a
23 little bigger so we don't clip off the
24 top. Thanks.

1 BY MR. BUCHANAN:

2 Q. Okay. All right. It doesn't get
3 any bigger, but at least it's a little more in
4 focus for you.

5 So what we see here is Walgreens
6 has a situation with their distribution center
7 severe enough that their license is suspended
8 for that particular distribution facility.

9 Do you recall that?

10 A. Yes.

11 Q. Okay. And then what you did is
12 you looked at, hey, what are we doing with them,
13 right?

14 MS. VANNI: Object to form.

15 BY MR. BUCHANAN:

16 Q. Do you see that?

17 A. Mm-hmm.

18 Q. And it shows here that over the
19 same period of time, or I guess really from
20 2009, 2010, 2011, your company, Qualitest
21 shipped how many pills, 83 million pills, right?

22 You see that?

23 A. Yes.

24 Q. Shipped 83 million pills to that

1 particular distribution facility that had its
2 license suspended in 2012, correct?

3 A. Yes, looks that way.

4 Q. Of 2009 there were 11 million
5 dosage units, right, Walgreens Jupiter, and you
6 know I think I misspoke. Let me restate this,
7 okay.

8 What's at the top, I believe, are
9 the dosage units shipped into Florida.

10 Do you see that?

11 A. Yes.

12 Q. 83 million dosage units shipped
13 into Florida, right? Am I reading it correctly?

14 A. I can't see.

15 Q. I wish I could do more to help
16 you on that.

17 A. Yes, it states that 83,000 --
18 83 million doses were sent to Florida in the
19 same time frame.

20 Q. And then in 2009 you shipped
21 11.6 million dosage units to the Jupiter
22 facility of Walgreens, right?

23 A. Yes.

24 Q. In 2010 you shipped 7 million to

1 that one?

2 A. Yes.

3 Q. And then apparently in 2011 they
4 went to another facility, right?

5 A. Yes.

6 Q. Okay. So over those two years
7 that we have data for, it doesn't go back prior
8 to 2009, there's some, you know, 18 million,
9 19 million, 18 and a half million, I guess to be
10 precise, dosage units of controlled substances
11 going to the facility that the DEA suspended its
12 license in 2012, correct?

13 A. Yes.

14 MS. VANNI: Object to form.

15 BY MR. BUCHANAN:

16 Q. Okay. And the allegation of the
17 DEA was that that facility and the reason for
18 the suspension of a license was that they failed
19 to maintain effective controls against diversion
20 of controlled substances, right?

21 A. Yes.

22 Q. And so prior to -- prior to 2013,
23 ma'am, I take it are you aware of any site
24 visits to Walgreens Jupiter?

1 A. Again, I don't know what the
2 sales team did, so I don't know if they went to
3 -- went there or not.

4 Q. We know the DEA's conclusion, at
5 least as reflected here, was that they failed to
6 be -- they were not maintaining effective
7 controls against diversion, right?

8 A. Yes.

9 Q. Okay. And had you asked for
10 copies of their suspicious order monitoring
11 protocols prior to 2013?

12 A. Again, I don't know.

13 Q. Okay. I mean, there's a list of
14 violations that are noted over several years in
15 this spreadsheet, correct?

16 A. Yes.

17 Q. For various entities, some are
18 retail pharmacies, some are distributors,
19 correct?

20 A. Yes, mm-hmm.

21 Q. And these are all obviously
22 events that have happened prior to the time of
23 this PowerPoint, right?

24 A. Yes, they are.

1 Q. And we could agree, couldn't we,
2 ma'am, that you're not aware of any request to
3 any of the entities on this sheet for request
4 for their suspicious order monitoring program or
5 practices prior to the times of these
6 violations, correct?

7 MS. VANNI: Objection.

8 THE WITNESS: I'm not sure. I
9 don't know.

10 BY MR. BUCHANAN:

11 Q. You don't have any information,
12 sitting here today, that you did so?

13 MS. VANNI: Objection.

14 THE WITNESS: Right, or did not.

15 BY MR. BUCHANAN:

16 Q. You have no information either
17 way?

18 A. Correct.

19 Q. Fair enough. Okay.

20 So let's go back to this
21 document. And so tab one was -- I'm sorry, at
22 606.4 we were just looking at violations, what
23 the allegations were, the consequences were and
24 then really where you were shipping product.

1 Do you see that there is
2 information for other entities had their
3 registrations pulled or suspended or there were
4 allegations against with regard to effective
5 controls against diversion on this sheet?

6 MS. VANNI: Object to the
7 colloquy.

8 THE WITNESS: Yes, that's what --
9 I mean, there are -- that's what this is
10 a list of violations, yes.

11 BY MR. BUCHANAN:

12 Q. There's too many for us to read
13 and it's almost too challenging to put on the
14 screen but --

15 A. Yes.

16 Q. -- just for the jury's benefit,
17 there are other manufacturers, other
18 distributors, other pharmacies referenced,
19 correct?

20 MS. VANNI: Object to form.

21 THE WITNESS: Yes.

22 BY MR. BUCHANAN:

23 Q. Okay. And there are other areas
24 where it is listed that you are, in fact,

1 shipping into that particular customer or
2 community. Do you see the column "What are we
3 doing" on page 606.5 and 606.4?

4 A. I do, yes.

5 Q. And there are other customers
6 that you were, in fact, fulfilling orders for
7 that had their licenses suspended or other
8 consequences?

9 A. Yes.

10 MS. VANNI: Object to form.

11 THE WITNESS: Keep in mind as
12 well that when -- when there is a -- a
13 letter of admonition or issued by DEA
14 for not conducting due diligence, for
15 example, that doesn't mean they're not
16 conducting due diligence on every
17 customer that they have. That means the
18 DEA found an example of that. If the
19 license is getting suspended, they've
20 probably found quite a few of them.
21 However, that license was also
22 reinstated, I believe, at a later date
23 by DEA. So at some point DEA felt that
24 they did have controls and gave them

1 back their license, basically.

2 BY MR. BUCHANAN:

3 Q. Right. I mean, but the concern,
4 obviously, and you've talked about it in your
5 own writings, we've seen it from the DEA
6 presentation, we have it in your oral testimony
7 today is a closed system, right?

8 A. Yes.

9 MS. VANNI: Object to form.

10 BY MR. BUCHANAN:

11 Q. So if we don't have a closed
12 system at a particular point in time, and I
13 think we looked at that spreadsheet where, I
14 mean, there were billions of pills being made
15 every year of controlled substances by
16 Qualitest, you'd agree?

17 MS. VANNI: Object to form.

18 THE WITNESS: Again, I can't
19 speak to those -- those numbers.

20 BY MR. BUCHANAN:

21 Q. I'll represent to you that the
22 data that's been produced to us reflects that
23 there were billions of pills of controlled
24 substances for hydrocodone and oxycodone that

1 were being shipped every year, okay, accepting
2 that representation, if a manufacturer -- if
3 anyone in this chain has their head in the sand
4 or isn't doing their job, then we don't have a
5 closed system?

6 MS. VANNI: Object to form.

7 THE WITNESS: Yes, however, a
8 violation from DEA --

9 BY MR. BUCHANAN:

10 Q. That's my question.

11 A. -- a letter of admonition does
12 not mean that somebody had their head in the
13 sand. Again, people make mistakes. Mistakes do
14 occur.

15 Q. Okay, okay. And so when mistakes
16 occur, okay, when there's negligence and --
17 withdrawn.

18 Let's go back to 606.14.

19 This document, again, just to
20 reorient the jury, because we've been hoping
21 around, at 606.1, this is the e-mail from
22 Mr. Shaffer to Mr. Brantley, people obviously in
23 your DEA compliance group, fair?

24 A. Yes.

1 Q. Okay. At 606.14 there's a
2 summary of the current SOMS process.

3 Do you see that?

4 A. Yes, I do.

5 Q. Okay. And this would be the SOMS
6 process for Qualitest as of -- prior to the
7 revamping, right?

8 A. Prior to the upgrades, yes.

9 MS. VANNI: Object to form.

10 BY MR. BUCHANAN:

11 Q. Okay. So the current SOMS
12 process is that -- was really directed at the
13 retail pharmacies, right?

14 MS. VANNI: Object to form.

15 THE WITNESS: Yes.

16 BY MR. BUCHANAN:

17 Q. Okay. So prior to revamping,
18 SOMS procedures and monitoring of the orders was
19 not tied into the wholesale and distributor
20 customers, correct?

21 MS. VANNI: Object to form.

22 THE WITNESS: No, I would
23 disagree with that from the aspect of
24 there was visibility -- in some cases

1 visibility to the inventories at the
2 wholesale level, so I think that
3 there -- they were being monitored, just
4 not part of this process.

5 BY MR. BUCHANAN:

6 Q. Okay. Well, without trying to
7 kind of look backwards and figure out how maybe
8 that could have been done, what was reflected on
9 this particular document, 606.14, as Qualitest's
10 current SOMS practices are these four bullet
11 points, correct?

12 A. Yes.

13 Q. Does the -- does this document
14 describe anything being done with wholesalers?

15 MS. VANNI: Object to form.

16 THE WITNESS: This document does
17 not.

18 BY MR. BUCHANAN:

19 Q. Okay. Retail pharmacies, so one
20 of the items is retail pharmacies under the
21 current SOMS process are based on a product
22 threshold amount, correct?

23 A. Correct.

24 Q. "Retail pharmacy threshold

1 amounts can be changed by the sales department,"
2 right?

3 A. Yes.

4 Q. And the threshold amounts are set
5 by the sales department, right?

6 A. Yes.

7 Q. And then the system holds the
8 order until reviewed, right?

9 A. Yes.

10 Q. Okay. And so this is the SOMS
11 process as memorialized by Qualitest as of this
12 point in time, correct?

13 A. Correct.

14 Q. Okay. The next page sets forth
15 the issues with that process, right?

16 A. The improvements that we'd like
17 to make.

18 Q. Well, what's written here is and
19 before somebody was asked to testify about it --

20 A. Wording.

21 Q. Yes, issues with the current
22 process, right?

23 MS. VANNI: Object to the
24 colloquy.

1 were, in fact, issues with the then current
2 process prior to the revamping of the system in
3 2013, right?

4 A. They were gaps that we internally
5 wanted to improve upon.

6 Q. Right, I mean, look, especially
7 if you're selling 33 billion pills of
8 hydrocodone, it's a pretty big gap not to be
9 looking at wholesalers and distributors for
10 SOMS, right?

11 MS. VANNI: Objection.

12 THE WITNESS: Really the
13 wholesalers and distributors are not --
14 they weren't the problem. The retail
15 pharmacies were the problem.

16 BY MR. BUCHANAN:

17 Q. Right, but --

18 A. So we were glad that we were
19 looking at retail pharmacies versus wholesalers.

20 Q. Well, you knew from the DEA back
21 all the way for years -- when you were at
22 Watson, you were looking at wholesalers?

23 A. They look at wholesalers on the
24 sale side separate from SOMS. If they weren't

1 is above the regulation.

2 Q. Okay. Something a responsible
3 company should do, right?

4 MS. VANNI: Object to form.

5 THE WITNESS: Possibly, yes.

6 BY MR. BUCHANAN:

7 Q. I mean, you list it as a
8 requirement, right?

9 A. Right, another example of
10 something that's not a requirement but that's
11 listed, yes.

12 Q. Okay. I guess if you're going to
13 make a promise to maintain effective controls of
14 diversion, you should do whatever you can do to
15 make sure these things don't leave the channel
16 of trade, right?

17 MS. VANNI: Object to form.

18 THE WITNESS: Yes.

19 BY MR. BUCHANAN:

20 Q. And stay in the closed system,
21 yes?

22 MS. VANNI: Object to form.

23 THE WITNESS: Yes.

24 BY MR. BUCHANAN:

1 start looking at chargeback data, right?

2 MS. VANNI: Object to form.

3 THE WITNESS: It's not a
4 regulation.

5 BY MR. BUCHANAN:

6 Q. Well, didn't they tell you you
7 need to do that?

8 MS. VANNI: Object to form.

9 THE WITNESS: They said you
10 should look at it. There's a difference
11 between should and must.

12 BY MR. BUCHANAN:

13 Q. Okay. And you'd agree, ma'am, as
14 a company that has been given a permission slip
15 by the U.S. government to stamp apparently
16 billions of pills every year, that you've got to
17 act consistent with the terms of that permission
18 slip, right?

19 MS. VANNI: Object to form.

20 THE WITNESS: Yes, with the
21 regulations.

22 BY MR. BUCHANAN:

23 Q. And the law, the statute, right?

24 A. Yes.

1 Q. Which says you must maintain
2 effective controls against diversion, right?

3 A. Yes.

4 Q. Okay. And so one of the tools of
5 information -- one of the classes of information
6 available to manufacturers for many of its
7 customers is chargeback data, right?

8 A. That's what DEA believes, yes.

9 Q. Another category of information
10 that's available to manufacturers is IMS data,
11 right?

12 A. Yes.

13 Q. And using IMS data, you can see
14 in percentage terms quantities that end user
15 pharmacies might be acquiring, whether they're
16 consistent with national averages, whether
17 they're above national averages or whether
18 they're below, right?

19 MS. VANNI: Object to form.

20 THE WITNESS: Yes.

21 BY MR. BUCHANAN:

22 Q. And that can raise red flags as
23 to whether a pharmacy, for example, is above
24 what you know the national average to be for

1 suspicious orders based on unusual size, order
2 pattern, deviation and unusual frequency,"
3 correct?

4 A. That's what it says, yes.

5 Q. And then the DEA SOMS feedback
6 you got on the next page, 581.6, was that "You
7 need to differentiate between the sales team
8 role and the DEA compliance role", right?

9 A. Yes, that's what it says.

10 Q. "You need to visit your
11 customers," right, and then this is an
12 exclamation point, right?

13 MS. VANNI: Object to form.

14 THE WITNESS: That's what it
15 says, yes.

16 BY MR. BUCHANAN:

17 Q. You got to put boots on the
18 ground from compliance with customers, right?

19 MS. VANNI: Object to form.

20 THE WITNESS: Yes, that's what
21 DEA would like to see.

22 BY MR. BUCHANAN:

23 Q. I'm assuming you put an
24 exclamation point in there for emphasis, right?

1 A. Yes.

2 Q. Okay. We have a problem, I guess
3 "we" there is the DEA -- are you using we to
4 refer to the DEA?

5 A. We to refer to our company.

6 Q. Well, it says, we have a problem
7 with companies using their sales team to conduct
8 these site visits.

9 A. Oh, I'm sorry, it is DEA.

10 Q. In that instance, you were using
11 the term we to refer to the DEA?

12 A. Yes.

13 Q. Right, and you understood the DEA
14 had a problem with companies using sales teams
15 to conduct the site visits, right?

16 MS. VANNI: Object to form.

17 THE WITNESS: They had a concern,
18 yes.

19 BY MR. BUCHANAN:

20 Q. Then it says you need to use the
21 chargeback data to understand what your
22 customers' customers are doing.

23 Did I read that correctly?

24 A. Yes.

1 THE WITNESS: Yes.

2 BY MR. BUCHANAN:

3 Q. And document your findings; is
4 that right?

5 A. Yes, which would not be
6 permitted.

7 Q. And you -- I'm sorry?

8 A. Which would not be permitted.
9 You can't visit your customers' customers.
10 They're not your customer.

11 Q. You can go to any pharmacy you
12 want and walk into, right?

13 A. Not to do a SOM visit, not to ask
14 questions about their business and their
15 program. That's your customer's job to ask
16 questions about their customer. So you can't
17 skip a line -- a link in the supply chain and go
18 to that next level --

19 Q. Well, we can agree you didn't
20 tell the DEA that in March 2013, did you, ma'am?

21 MS. VANNI: Object to form.

22 THE WITNESS: We didn't get into
23 that level of detail in the
24 conversation.

1 Q. Okay. So, certainly, if you're
2 going to have an effective program, you've got
3 to have people as part of this process, right?

4 MS. VANNI: Object to form.

5 THE WITNESS: We had people as
6 part of the process. They were just in
7 sales and the perception was not good,
8 so we moved them into compliance.

9 BY MR. BUCHANAN:

10 Q. Right.

11 And you're going to have to put
12 boots on the ground too and do due diligence
13 visits and do all kinds of stuff, right?

14 MS. VANNI: Object to form.

15 THE WITNESS: So that sales
16 doesn't have to do it, yes.

17 BY MR. BUCHANAN:

18 Q. Well, one of things we know you
19 did is you brought in Mr. Brantley, right?

20 A. Yes, I did.

21 Q. I mean, you needed -- I mean,
22 what was his title?

23 A. He was a manager of the SOM
24 program.

1 Q. Was there a manager of the SOM
2 program in title, prior to that point in time?

3 A. Not that title, no.

4 Q. Right.

5 There was no manager of the SOM
6 program in Qualitest prior to September of
7 2014 -- 2013, excuse me?

8 A. Yes, that's correct. Doesn't
9 mean it wasn't being done.

10 Q. All right. So -- and someone
11 else is going to decide that, ma'am, so let's --
12 can we agree there was nobody at Qualitest who
13 had that title prior to September of 2013?

14 A. Not that title, correct.

15 Q. Okay. And what you noted here is
16 you're going to hire individuals to support the
17 program, right?

18 A. Yes.

19 Q. One of the things you did was you
20 hired somebody as director of SOMS,
21 Mr. Brantley?

22 A. Manager of SOMS, yes.

23 Q. There you go.

24 "All individuals on board and

1 actively working on other aspects of the
2 program," right?

3 A. Yes.

4 Q. One of things you needed was
5 personnel training, right?

6 A. Yes.

7 Q. You had to implement SOPs, right?

8 A. Yes.

9 Q. You had to develop
10 questionnaires, distribute questionnaires, get
11 responses from questionnaires for their customer
12 SOMS data, right?

13 A. Yes.

14 Q. Okay. You had to create customer
15 boundaries, that was one of the things you were
16 going to do, right?

17 MS. VANNI: Object to form.

18 THE WITNESS: That was using the
19 IMS data.

20 BY MR. BUCHANAN:

21 Q. Okay. So to create as part of
22 this individual customer boundary so that you'd
23 have flags as to unusual order sizes when they
24 went beyond boundaries for various classes of

1 Q. Okay. And so a demo was given to
2 the finance folks. You said an agreement was
3 reached with them, right?

4 A. Yes.

5 Q. IT resources were implemented to
6 capture the feed, right?

7 MS. VANNI: Object to form.

8 THE WITNESS: Yes.

9 BY MR. BUCHANAN:

10 Q. And then you're going to plan to
11 further develop this with leadership, I guess
12 that's Mike and Trey?

13 A. That's the sales team.

14 Q. Got you.

15 That was Phase III, right, and
16 that's chargeback data?

17 A. Yes.

18 Q. That was another new addition to
19 the program, right?

20 MS. VANNI: Object to form.

21 THE WITNESS: That was one new
22 addition to the program, one improvement
23 to the existing program, yes.

24 BY MR. BUCHANAN:

1 Q. All right. And we've talked
2 about what the old program was, and this talked
3 about what it covered, and now we're talking
4 about your various phases for revamping it,
5 right?

6 A. Yes, the enhancements to the
7 existing program.

8 Q. Okay. Next, Phase IV, boots on
9 the ground, right?

10 A. Yes.

11 Q. Okay. "Customer Due Diligence
12 Visits," right, know your customer?

13 A. Yes, correct.

14 Q. Okay. Because there were some
15 direct customers that were in the DEA binder,
16 you know, some big distributors, right?

17 A. Yes.

18 Q. There were six, I think, charts
19 that reflected McKesson. There were five that
20 reflected CVS. There were two that reflected HD
21 Smith, right?

22 A. Our intent was to target the
23 customers that were identified in there first,
24 yes.

1 Q. Right. And these have been
2 called out in the DEA binder as, hey, these are
3 people that you're buying they're well above the
4 norms, right?

5 MS. VANNI: Object to form.

6 THE WITNESS: They had large
7 quantities that needed to be researched
8 or DEA thought they were large
9 quantities, yes.

10 BY MR. BUCHANAN:

11 Q. Right. So you were going to put
12 boots on the ground first to customers that had
13 been flagged, right?

14 MS. VANNI: Object to form.

15 BY MR. BUCHANAN:

16 Q. In that DEA presentation, right?

17 A. Yes.

18 Q. But you also sent out a dear
19 valued customer to every customer, correct?

20 A. Correct.

21 Q. That was the October 18 letter
22 that we looked at earlier today, correct?

23 A. The October, yes, 2013.

24 Q. I meant October 18, 2013 letter,

1 wording for that particular vendor, that's their
2 standard wording, yes.

3 Q. But do you agree, I mean, if
4 you're going to have a system for detecting
5 suspicious orders, that it should be tested,
6 validated and defensible?

7 A. Any computer system should be
8 validated. It's an FDA requirement, yes.

9 Q. Well, I'm not talking about FDA
10 requirements, ma'am.

11 I just want to know do you agree
12 with regard to suspicious order monitoring, the
13 system should be tested, validated and
14 defensible?

15 A. Yes.

16 Q. Okay, good. Statistically
17 defensible, you agree?

18 A. Yes.

19 Q. Okay. And they advised further
20 that you should not provide customers for the
21 reason their orders are held or pended as this
22 may result in customers working to avoid the one
23 item that caused the order to be declined.

24 Do you see that?

1 A. That's correct.

2 Q. Do you agree that --

3 A. That's common sense.

4 Q. Yeah, I mean, because if you
5 share with customers what the thresholds are
6 that you've set, they can structure their orders
7 in a way so that they stay below the thresholds
8 all the time but get to the same place in a
9 different way?

10 A. Right, which is why we didn't
11 share those.

12 Q. Right. So sharing thresholds,
13 bad practice, right?

14 A. Yes.

15 Q. Okay. Working with orders to --
16 working with customers to structure their orders
17 so they stay within thresholds is not a good
18 practice?

19 A. No, it's not.

20 MS. VANNI: Object to form.

21 BY MR. BUCHANAN:

22 Q. I mean, the manufacturer or the
23 distributor should not be working with its
24 primary customer to structure its order in a way

1 to stay within whatever the red flag thresholds
2 are, right?

3 MS. VANNI: Object to form.

4 THE WITNESS: No, that defeats
5 the purpose of the program.

6 BY MR. BUCHANAN:

7 Q. Right.

8 That's a very bad practice,
9 right?

10 A. Yes.

11 Q. And if you're doing that kind of
12 practice and you're certainly not maintaining
13 effective controls against diversion, right?

14 MS. VANNI: Object to form.

15 THE WITNESS: That's correct.

16 However, customers can, over time, if
17 they're a regular customer, kind of
18 figure out what your threshold is. You
19 don't communicate it to them, but if
20 they're smart and they keep track of it,
21 they can technically figure it out.

22 BY MR. BUCHANAN:

23 Q. But as a manufacturer, you need
24 to be vigilant to make sure your customers are

1 MS. VANNI: Object to the form.

2 BY MR. BUCHANAN:

3 Q. And you forwarded along the
4 Cegedim report and conclusions and
5 recommendations, right?

6 A. Yes, looks like I did.

7 Q. And so the PowerPoint begins on
8 -- I'm sorry, 1052.7.

9 MR. BUCHANAN: If you can go
10 there, please, Bradley, for everyone's
11 benefit.

12 BY MR. BUCHANAN:

13 Q. And you've got your agenda on the
14 next page and an overview of the Cegedim report,
15 right?

16 A. Yes.

17 Q. And then you've got the first
18 bullet on page 1052.10.

19 A. Yes.

20 Q. Called out for your boss, right?

21 A. Yes.

22 Q. Okay. No qualifiers, right?

23 MS. VANNI: Objection.

24 THE WITNESS: Just repeating what

1 Q. Including geographical
2 distributions. These are your recommendations
3 before the DEA ever sat down with you, right?

4 A. Right, the geographical, mm-hmm,
5 yes.

6 Q. As somebody in the industry with
7 experience in SOMS and also anti-diversion
8 efforts, right?

9 A. And sitting at DEA conferences,
10 yes.

11 Q. Okay. And Phase III, you're
12 going to start doing on-site customer
13 evaluations, right?

14 A. Yes.

15 Q. That was before you met with the
16 DEA, right?

17 A. Those were things we were --

18 Q. On-site customer evaluations?

19 A. Things we were moving towards,
20 yes.

21 Q. 1052.15, right?

22 A. Yes.

23 Q. And things that were not
24 happening before?

1 A. Right.

2 MS. VANNI: Form.

3 THE WITNESS: Things that were
4 not happening by the compliance team or
5 things that I wanted to improve.

6 BY MR. BUCHANAN:

7 Q. Right.

8 Well, certainly, here it doesn't
9 note that our sales force is doing on-site
10 customer evaluations for compliance, right?

11 A. Didn't need to be. It was an
12 internal document, and that was well known.

13 Q. And next you proposed as Phase
14 III accessing chargeback data, correct, ma'am?

15 A. Yes.

16 Q. Before the DEA ever even told
17 you, right?

18 A. Correct. It was brought up at
19 other conferences.

20 Q. Right. So you didn't need this
21 meeting with the DEA in March to know that,
22 right?

23 A. Well, I know that other
24 manufacturers --

1 MS. VANNI: Object to form.

2 THE WITNESS: -- were using
3 chargeback data, and it was something
4 that I was looking into.

5 BY MR. BUCHANAN:

6 Q. Right. So one of the things you
7 were going to do is you're going to start
8 accessing chargeback data and also third party
9 data sources, right?

10 A. IMS, yes.

11 Q. IMS, right.

12 This provides visibility of
13 product flow down the customer stream and allows
14 for enhanced compliance for the "Know Your
15 Customer" requirement of the DEA, correct?

16 A. I thought it would, yes.

17 Q. Right.

18 And so as of 2013, before you
19 ever met with the DEA, you were aware of the
20 know your customer obligation, correct?

21 MS. VANNI: Object to form.

22 THE WITNESS: Yes.

23 BY MR. BUCHANAN:

24 Q. You were aware of the

1 A. This is not talking about the
2 current state of the business. It's talking
3 about the requirements for DEA.

4 Q. Let's go to 1071.8.

5 There's an analysis of current
6 weaknesses, right?

7 A. Yes.

8 Q. Okay. Weaknesses and there's
9 strengths and opportunities and threats and all
10 kinds of things. I'm not going to have time to
11 go through all of this with you.

12 One of the weaknesses at this
13 point in time was you had a lack of resources,
14 right?

15 A. Yes.

16 Q. Limited talent pool and limited
17 investments in the group, right?

18 MS. VANNI: Object to form.

19 THE WITNESS: I'm not sure what
20 the investments means, to be honest, but
21 the talent pool, yes.

22 BY MR. BUCHANAN:

23 Q. Another weakness you had was a
24 "lack of training & compliance first culture,"

1 right?

2 A. Yes.

3 Q. Compliance first culture meaning
4 we got to do this, it's really important that we
5 do it, right?

6 MS. VANNI: Object to form.

7 THE WITNESS: I'm again not sure
8 what first culture means. Some of those
9 words, I have a feeling Sanjay
10 participated in this.

11 BY MR. BUCHANAN:

12 Q. Okay. And what's the next
13 weakness?

14 A. "Inadequate SOMS."

15 We wanted it to be stronger.

16 Q. Let's be clear, the words you
17 wrote were "inadequate SOMS," correct, ma'am?

18 A. Correct. Current program is not
19 adequate for my standards.

20 Q. Okay. And what we're looking at
21 here is could you remind us, ma'am, is this
22 before or after you sat down with the DEA?

23 A. This is before.

24 Q. Okay. So even before you sat

1 down with the DEA and spent the three hours in
2 DC with them, I mean, you knew you had
3 inadequate SOMS, right?

4 MS. VANNI: Object to form.

5 THE WITNESS: I knew I had
6 improvements that I wanted to make.

7 BY MR. BUCHANAN:

8 Q. I understand that's how it's
9 characterized here in the record, ma'am, but
10 what you wrote to your boss is we have
11 inadequate SOMS correct?

12 MS. VANNI: Objection.

13 THE WITNESS: That's what the
14 document says versus what is --

15 BY MR. BUCHANAN:

16 Q. And that's what you put into it?

17 A. Yeah.

18 Q. Okay. And what you forwarded up
19 the food chain in Qualitest at that point in
20 time, correct?

21 MS. VANNI: Objection.

22 THE WITNESS: Correct, because
23 improvements we wanted to make.

24 BY MR. BUCHANAN:

1 MS. VANNI: Object to form.

2 THE WITNESS: And I had very high
3 goals and standards.

4 BY MR. BUCHANAN:

5 Q. And we can agree not only your
6 standards that was inadequate by but inadequate
7 by the consultants who you met with, correct?

8 MS. VANNI: Object to form.

9 THE WITNESS: Because they wanted
10 the business, yes.

11 BY MR. BUCHANAN:

12 Q. Okay. We can agree before the
13 DEA told you that your SOMS system was
14 inadequate, you had concluded it was inadequate,
15 correct?

16 MS. VANNI: Object to form.

17 THE WITNESS: DEA did not say the
18 SOMS system was inadequate. If they
19 found it to be inadequate, we would have
20 gotten violations. We did not get
21 violations for our SOM system.

22 MR. BUCHANAN: Move to strike.

23 BY MR. BUCHANAN:

24 Q. Okay. We have the DEA statements

1 (Brief recess.)

2 THE VIDEOGRAPHER: We're now back
3 on the record. The time is 3:39 p.m.

4 (Document marked for
5 identification as Par-Norton Deposition
6 Exhibit No. 17.)

7 BY MR. BUCHANAN:

8 Q. Ma'am, I'm passing you over what
9 we're marking as Exhibit 17 to your deposition.
10 Are you miked up, ma'am?

11 A. Yes.

12 Q. You are. Okay. Better than I.
13 It's a document from early 2013,
14 right?

15 A. Yes.

16 Q. An e-mail from yourself to Sanjay
17 Patel?

18 A. Yes, correct.

19 Q. Copied to your boss, Jill
20 Connell?

21 A. Yes.

22 Q. Was Sanjay also your boss?

23 A. He was when Jill left the
24 company, Sanjay was my boss.

1 Q. Okay. This is today's meeting,
2 and then it's got a list of action items.

3 Do you see that?

4 A. Yes, I do.

5 Q. Okay. Let's roll forward to the
6 body of this, and it's January 4, 2013, just to
7 orient ourselves in time. This would have been
8 prior to the meeting with DEA when you got that
9 thick binder that we spoke about, right?

10 A. Yes.

11 Q. This would have been prior to the
12 interactions you had with the Buzzeo group in
13 mid-January 2013, right?

14 A. Yes.

15 Q. Okay. Let's go forward to -- if
16 we could, page 574.24, right.

17 So prior to this meeting and this
18 audit you had with Buzzeo, you were categorizing
19 potential failure modes and effects, visibility
20 rating, severity rating, et cetera, right?

21 A. Yes.

22 Q. Okay. And so with regard to your
23 suspicious order monitoring system, you note
24 that it was built in pieces and only applies to

1 the retail side of the business, correct, ma'am?

2 A. SOMS does, yes.

3 Q. Okay. The "suspicious order
4 monitoring program was built in pieces and only
5 applies to the retail side of the business."

6 Did I read that correctly?

7 A. You did.

8 Q. DEA requires it to apply to all
9 customers.

10 Do you see that?

11 A. Correct, which is what we had --

12 Q. Your words, right?

13 A. Yes.

14 Q. Okay. "In addition, the current
15 system has had two issues in the past year that
16 resulted in controlled product being released
17 that should not have been."

18 Do you see that?

19 A. Yes, I do.

20 Q. That's not good, right?

21 MS. VANNI: Object to form.

22 THE WITNESS: That's what it
23 says, yes.

24 BY MR. BUCHANAN:

1 Q. Not good, right?

2 MS. VANNI: Objection.

3 THE WITNESS: Not good.

4 BY MR. BUCHANAN:

5 Q. Okay. "The system needs to be
6 revamped," right?

7 A. Yes.

8 Q. Remember we talked earlier about
9 the system needing to be revamped?

10 A. Yes, improvements needed to be
11 made.

12 Q. And what you wrote was revamped,
13 right?

14 MS. VANNI: Object to form.

15 THE WITNESS: Yes.

16 BY MR. BUCHANAN:

17 Q. First, all customers have to be
18 added, right?

19 A. Yes.

20 Q. "IMS data and chargeback data
21 incorporated," correct?

22 A. That's what it says, yes.

23 Q. "And eventually a contracted
24 customer assessment firm hired or an on-site

1 SOMS specific individual to perform these
2 assessments."

3 Did I read that correctly?

4 A. Yes, you did.

5 Q. You knew all of that on your own
6 without having to go up to DC and meet with the
7 DEA, right?

8 MS. VANNI: Object to form.

9 THE WITNESS: Yes, we were trying
10 to make a lot of improvements before DEA
11 even got involved.

12 BY MR. BUCHANAN:

13 Q. Okay. How to revamp it, right?

14 A. How to make improvements.

15 Q. Okay. And previously you
16 characterized the old system as inadequate,
17 correct?

18 MS. VANNI: Object to form.

19 THE WITNESS: Yes.

20 BY MR. BUCHANAN:

21 Q. Okay. Then we look at visibility
22 rating and severity rating, right?

23 A. Yes.

24 Q. You've been in corporate land for

1 a while, right?

2 MS. VANNI: Object to form.

3 THE WITNESS: Yes.

4 BY MR. BUCHANAN:

5 Q. This is one way you do a risk
6 assessment, right?

7 A. Yes.

8 Q. Look at the visibility of the
9 problem, look at the severity of the problem and
10 then give it a risk score, right?

11 A. Correct.

12 Q. And the risk score you gave this
13 for visibility was a 5, right?

14 A. Yes.

15 Q. And severity was a 5, right?

16 A. Yes.

17 Q. And the total risk rating was 25,
18 right?

19 A. Yes.

20 Q. Highest of anything -- highest of
21 any risk, right?

22 MS. VANNI: Objection.

23 THE WITNESS: Twenty-five was the
24 highest in the document, mm-hmm.

1 Q. Thank you.

2 It's a couple years before you
3 had that sit down with the DEA where you got
4 called into DC, right?

5 A. Yes.

6 MS. VANNI: Object to form.

7 BY MR. BUCHANAN:

8 Q. Okay. So you had that knowledge
9 certainly in 2011, right, ma'am?

10 MS. VANNI: Object to form.

11 THE WITNESS: Yes.

12 BY MR. BUCHANAN:

13 Q. Okay. He stated -- he states,
14 "Yet, in his opinion, nothing has changed on the
15 manufacturer's side in regards to the way we do
16 reconciliations."

17 Do you see that?

18 A. Yes, I do.

19 Q. "He stated that we have the
20 public's trust in our hands and we need to be
21 sure we are staying ahead of the curve by
22 monitoring current diversion trends and
23 tightening our processes."

24 Do you see that?

1

1

1



1

3



5

114

103

101

██████████

103

114

7

114

11

114

5

114

11

114

5

114

7

© 2006 The Authors

© 2006 The Authors
Journal compilation © 2006 Blackwell Publishing Ltd

11

10

7

11
